Effects of Oxandrolone on Outcome Measures in the Severely Burned: A Multicenter Prospective Randomized Double-Blind Trial

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Severe burns induce pathophysiologic problems, among them catabolism of lean mass, leading to protracted hospitalization and prolonged recovery. Oxandrolone is an anabolic agent shown to decrease lean mass catabolism and improve wound healing in the severely burned patients. We enrolled 81 adult subjects with burns 20% to 60% TBSA in a multicenter trial testing the effects of oxandrolone on length of hospital stay. Subjects were randomized between oxandrolone 10 mg every 12 hours or placebo. The study was stopped halfway through projected enrollment because of a significant difference between groups found on planned interim analysis. We found that length of stay was shorter in the oxandrolone group (31.6 ± 3.1 days) than placebo (43.3 ± 5.3 days; $P < .05$). This difference strengthened when deaths were excluded and hospital stay was indexed to burn size (1.24 ± 0.15 days/% TBSA burned vs 0.87 ± 0.05 days/% TBSA burned, $P < .05$). We conclude that treatment using oxandrolone should be considered for use in the severely burned while hepatic transaminases are monitored. (J Burn Care Res 2006;27:131–139)

Severe burn results in an inflammatory, catabolic state that induces loss of lean body mass, strength, and sense of well-being. Increased production of catabolic hormones such as epinephrine and cortisol and decreased levels of anabolic hormones such as growth hormone and testosterone contribute to the postburn hypermetabolic response. Early aggressive nutritional support to patients while they are hospitalized can attenuate some of these losses, but severely burned patients are still hampered by this profound response, which can last for months into recovery.[1]

A number of anabolic hormones have been used effectively to abrogate catabolism in patients after severe injury when given over a portion of the hospital stay. These include insulin,[2] growth hormone,[3] insulin-like growth factor-I,[4] oxandrolone,[5] and testosterone.[6,7] Of these, oxandrolone appears to be the best candidate for use to increase net protein synthesis during hospitalization after severe injury for several reasons: 1) It is less expensive than growth hormone and insulin-like growth factor, thus providing a fiscal benefit. 2) It is administered orally and, thus, it is better tolerated than agents requiring intravenous ac-

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cess (insulin, insulin-like growth factor) or injections (growth hormone, testosterone). 3) Its side effect profile is well described, and it holds much less virilization potential than testosterone.

Oxandrolone is an analog of testosterone, which has been used clinically to treat muscle wasting in AIDS wasting myopathy,[7] hepatic failure,[8] incapacitating chronic obstructive pulmonary disease,[9] in burned children,[10] and burned convalescing adults.[11] All of these studies showed that the use of oxandrolone is safe, and they demonstrated the utility of oxandrolone in clinical conditions of decreased strength or muscle wasting. When oxandrolone was given to burned adults during acute hospitalization, beneficial effects of improved nitrogen balance and decreased weight losses were observed.[3,5,12]

Although studies of the effectiveness of oxandrolone in patients with burns have produced very encouraging results, many important questions remain to be answered. Most importantly, the preliminary studies involved small numbers of patients, and the results need to be reproduced in a larger study. In addition, outcome measures such as decreased length of stay, decreased ventilator days, and/or decreased hospital charges need to be demonstrated.

Although nearly all severely burned patients receive treatments to improve functional outcomes, these efforts are likely to be hampered by the loss of muscle mass and therefore strength as the result of catabolism. We propose that treatment with oxandrolone throughout the acute hospitalization will enhance overall well-being such that hospitalization time will decrease. This study will have a direct impact on the restoration of physical capacity and, in turn, the ability of burned people to resume normal activities. The ultimate significance of this work may be the reduction of health care and compensation expenses associated with burn treatment.

The primary objective of this multicenter study was to examine the effect of oxandrolone on length of stay for burn patients with 20% to 60% TBSA burns as a measure of beneficial clinical outcome with this anabolic treatment. We also examined adverse events related to the use of oxandrolone. This study was designed to be performed without industry support.

METHODS

This study was performed at 14 burn centers, each of whom received approval to conduct the study by their respective institutional review boards (see acknowledgments). Informed written consent was obtained from each patient or surrogate before enrollment into the study. Inclusion criteria were as follows: man or woman age 18 years or older, acute burn injury of greater than 20% TBSA, ability to begin oral or enteral nutrition within 5 days of injury, no concurrent injuries apart from burn/inhalation injury that could produce long term disabilities (eg, spinal cord injury, anoxic brain injury). Exclusion criteria were primary electrical or chemical injury, pregnancy, history of chronic liver disease, renal failure, cancer, recent/ongoing use of glucocorticoids or anabolic steroids, or participation in another research study that may confound the results of this study in the opinion of the principal investigator.

Design

This study was designed as a multicenter prospective randomized double-blind investigation. Eligible subjects were approached for consent within 5 days of injury, at which time they were assigned a study number within the stratification schema. Stratification criteria were by center, age in years (18–44, 45–64, 65 or older), and burn size (20–30% TBSA, 31–40%, 41–50%, and 51–60%), which was performed to ensure equitable distribution between groups. After enrollment, subjects were assigned randomly to one of two arms, placebo or 10 mg of oxandrolone given by mouth or enteral feeding tube every 12 hours beginning 5 days after injury. A 5-day delay was chosen to enable the development of the relatively chronic hypermetabolic response and to avoid exigencies common in the resuscitative phase. The placebo used was sucrose. In the event that oral intake was not available, oxandrolone was dissolved in ethanol for delivery via enteral feeding tube. Each study center's research pharmacy was responsible for randomization and administration of the drug. Placebo or oxandrolone was continued until hospital discharge.

Enteral or oral nutrition was given to all subjects at the discretion of the principal investigator or his/her associates. Hepatic transaminases were drawn when clinically indicated. Subjects underwent burn wound excision and/or skin grafting at the discretion of the attending physician.

Data Collection

The following information was collected on each enrolled subject: age, sex, race, admission height and weight, total and full-thickness burn percentage, presence or absence of inhalation injury, cause of burn, number of surgical procedures, length of hospitalization in days, survival, total hospital charges, days of ventilator support, and discharge disposition. Full-thickness area was verified by inspection of operations for skin grafting by the study principal inves-

tigator. Inhalation injury definition was at the discretion of the site principal investigator, which was agreed to be physical signs of smoke inhalation with a consistent history. Hospital days included total time in the acute care hospital of the site principal investigator. Investigators also were required to submit documentation of complications their patients encountered during treatment. Serious adverse events were reported to respective institutional review boards and to the principal investigator for the study (S.E.W.). All serious adverse events were reviewed for relevance to the study by a safety committee that did not have knowledge of group designation (S.E.W., J.R.S., and A.P.S.).

Statistical Methods and Data Analysis

Initial determination of sample size was determined using a *t*-test prediction assuming a 10% improvement in hospital stay with a variance of 20%. To meet a power of $\beta = 0.8$, it was predicted that 64 subjects would be required in each group to reach significance set at a level of $P = .05$. To account for protocol violations, we planned to enroll 70 subjects per group. We also planned to perform an interim analysis, blinded to designation of the group (J.J.) when 75 subjects were enrolled into the study to assess for greater effect than estimated and potential safety issues.

Data were analyzed using methods that enabled a description of the subject population and a comparison of outcome measures between groups. Descriptive summaries are presented by treatment group for demographic and clinical background variables, outcome variables, and safety endpoints. Comparisons between groups was done by χ^2, Mann-Whitney rank sum test, or *t*-test where appropriate. All subjects randomized and enrolled were included in the analysis as intent to treat. Data are listed as mean ± standard error of the mean where appropriate.

All study records were maintained in a secure office and/or on a password-protected computer by respective study coordinators. Subjects were identified only by unique study identifier on all data forms (paper and electronic) shared with the representatives of the multicenter group involved with data analysis. Completed data forms were sent to investigators at the University of Utah, which were forwarded to Dr. Jeng at the Washington Burn Center for interim analysis. At completion of the study, records were sent to the studies' principal investigator at the University of Texas Medical Branch for final analysis.

RESULTS

Eighty-one subjects completed the study while being treated at one of 14 different burn centers. Seventy-three percent of subjects were ages 18 to 44 years, 19% were 45 to 64 years, and 9% were older than 64 years of age. Forty-one percent of subjects sustained burns between 20% and 30% TBSA, 25% between 31% and 40% TBSA, 20% between 41% and 50% TBSA, and 15% between 51% and 60% TBSA (Table 1). Subject accrual by study center is listed in Table 2.

After stratification, subjects were assigned randomly to receive either placebo or oxandrolone from 5 days after burn throughout the rest of the hospitalization. Thirty-five patients received placebo, whereas 46 received oxandrolone. Characteristics of the groups are listed in Table 3. The groups were well matched in terms of age, burn size, weight, height, sex, cause of burn, and inhalation injury.

Length of hospital stay was the principal outcome indicator. In September 2003, when data were complete for 75 subjects, an interim analysis was performed that indicated a significant difference between groups. Subjects completing hospitalization before September 1, 2003, were used for further analysis to avoid issues with blinding. Six more subjects were added to the final analysis by these criteria. We found that length of hospital stay was significantly shortened when the use of oxandrolone was begun 5 to 7 days after admission. When deaths were excluded, the significant difference between groups strengthened (Figure 1). When length of stay was indexed to burn size, treatment withoxandrolone was found to be further associated with diminished length of hospital stay (Figure 2). Length of hospital stay for both groups combined was 37 ± 3 days or 1.03 ± 0.08 days/% TBSA burn, which is in keeping with established norms.[13] Subgroup analysis of stratification

Table 1. Stratification scheme for trial entry and randomization

	Age, years			
TBSA burn, %	**18–44**	**45–64**	**>64**	**Total**
20–30	22 (8/14)	7 (4/3)	4 (2/2)	33 (14/19)
31–40	13 (4/9)	5 (3/2)	2 (1/1)	20 (8/12)
41–50	14 (5/9)	2 (2/0)	0	16 (7/9)
51–60	10 (6/4)	1 (0/1)	1 (0/1)	12 (6/6)
Total	59 (23/36)	15 (9/6)	7 (3/4)	

Number of subjects in each portion of the stratification are listed, with subjects receiving placebo and oxandrolone, respectively, listed in parentheses.

Table 2. Subjects enrolled at each study site

Site	No. Subjects
1	2
2	9
3	9
4	2
5	4
6	4
7	5
8	8
9	2
10	10
11	13
12	6
13	4
14	3

Table 3. Group demographics

Demographic Data	Placebo	Oxandrolone	*P* Value
Subjects, no.	35	46	
Age, years	40 (3)	39 (2)	0.825
Admit weight, kg	87 (3)	84 (3)	0.453
Height, cm	173 (4)	173 (2)	0.984
Sexr, men/women	26/9	35/11	0.941
Race			
European American	27	40	
African American	5	3	
Native American	2		
Hispanic American		1	
Asian American	1		
Unknown		2	
TBSA burned, %	36 (2)	35 (2)	0.612
Full-thickness burn, % TBSA	18 (2)	14 (2)	0.176
Cause of burn			
Flame	33	40	
Scald	1	3	
Grease	1	1	
Contact		2	
Inhalation injury, yes/no	12/23	14/32	0.899

Data are listed in means where appropriate with standard error in parentheses.

groups either individually or grouped by age or burn size did not have sufficient statistical power to detect a difference between groups (data not shown). The trial was closed to further enrollment at this point.

To further assess differences between groups, ventilator days, number of surgical procedures, discharge disposition, and hospital charges were calculated. Data are as follows. Subjects receiving placebo were on ventilatory support for 18 ± 4 days, whereas those receiving oxandrolone 13 ± 3 ($P = .282$ by Mann-Whitney rank sum test). Data were not available for two subjects in each group. Number of surgical procedures were 4.0 ± 0.6/subject in the placebo group and 2.2 ± 0.3/subject in the oxandrolone group ($P = .015$ by Mann-Whitney rank sum test). Graphical representation by frequency distribution of the percentage of patients in each group requiring a certain number of surgeries (eg, 0, 1, 2, 3 surgeries) is depicted in Figure 3. This representation shows that the percentage of patients is skewed toward more surgeries in the placebo group that follows a more bimodal distribution than the oxandrolone group, with another peak at seven surgerys.

Twenty of 35 subjects receiving placebo were discharged to home, whereas 32 of 46 subjects receiving oxandrolone subjects were discharged to home ($P =$

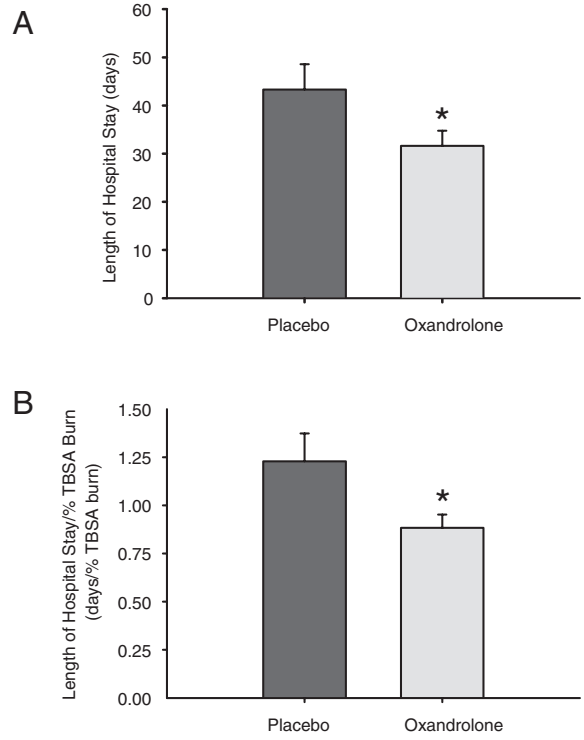

Figure 1. A. Length of hospital stay in those receiving placebo (43.3 ± 5.3 days) or oxandrolone (31.6 ± 3.1 days). *Indicates a significant difference between groups ($P = .042$ by Mann-Whitney rank sum test). B. Length of hospital stay indexed to TBSA burn in those receiving placebo (1.23 ± 0.15 days) or oxandrolone (0.88 ± 0.07 days). *Indicates a significant difference between groups ($P = .032$ by Mann-Whitney rank sum test).

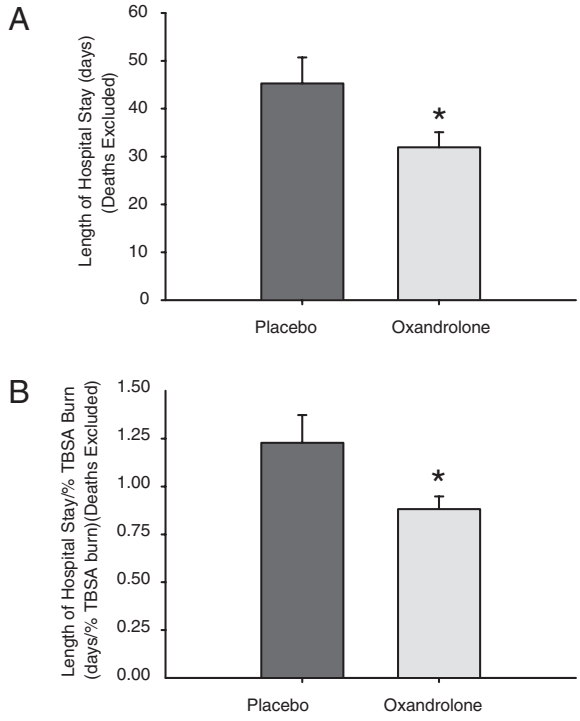

Figure 2. A. Length of hospital stay, excluding deaths in those receiving placebo (45.3 ± 5.4 days) or oxandrolone (32.0 ± 3.1 days). *Indicates a significant difference between groups ($P = .035$ by Mann-Whitney rank sum test). B. Length of hospital stay excluding deaths indexed to TBSA burn in those receiving placebo (1.29 ± 0.15) or oxandrolone (0.88 ± 0.07). *Indicates a significant difference between groups ($P = .015$ by Mann-Whitney rank sum test).

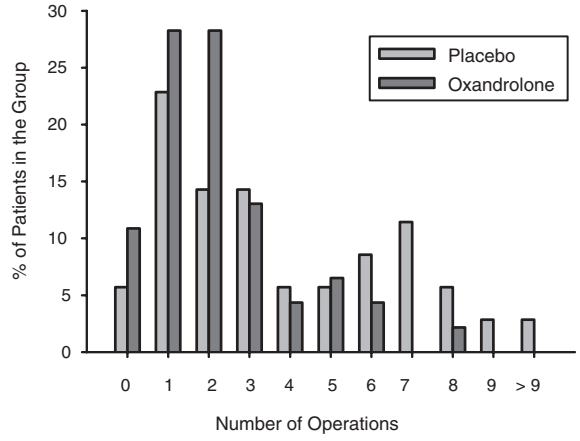

Figure 3. Percentage of patients in each group ranked by number of surgeries received for acute wound closure.

0.357 by χ^2). Hospital charges were $262,671 ± 57,442 for the placebo group and $227,588 ± 30,086 for the oxandrolone group ($P = .623$). When indexed to burn size, data were $6982.44 ± 1165.69/% TBSA burn for the placebo group and $6190.00 ± 644.75/% TBSA burn for the oxandrolone group ($P = 0.592$). Data were not available for 9 subjects in the placebo group and 12 in the oxandrolone group.

Adverse events and complications listed by investigators were those common to burn patients. Adverse events were reported in 12 of 35 subjects in the placebo group and 11 of 46 in the oxandrolone group ($P = 0.437$). Complications were reported in 20 of 35 subjects in the placebo group and 24 of 46 in the oxandrolone group ($P = 0.846$). Complications are listed in Table 4. All adverse events were considered to be complications in this list. None of the serious adverse events reported by the investigators to the safety committee were deemed to be clearly related to treatment. In considering infectious complications alone, subjects receiving placebo had 29 incidences whereas the subjects receiving oxandrolone had 32. On qualitative assessment, the subjects receiving oxandrolone appeared to have more skin-related complications of cellulitis and the development of skin rashes (not statistically significant). Renal failure also might be more prevalent (also not statistically significant). Unfortunately, this size study does not have the statistical power to draw any firm conclusions in these regards.

Increases in hepatic transaminases have been reported with anabolic steroid treatment. To evaluate this possibility, transaminase levels were assessed. Ten of 14 centers reported levels in some or all subjects. Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) levels are represented in Figures 4 and 5. No significant differences were found between groups except in week 8 and greater. For AST, 62 of 119 values were out of the normal range (5–30 mg/dl) in the placebo group, and 69 of 114 in the oxandrolone group ($P = .254$). For ALT, 66 of 118 values were out of the normal range (5–30 mg/dl) in the placebo group, and 52 of 110 in the oxandrolone group ($P = .240$). To arbitrarily identify significant hepatic damage at values for AST and ALT at greater than 100 mg/dl, 9 and 6 values were above this range for AST and ALT in the placebo group respectively, and 11 ($P = .738$) and 21 ($P = .002$) for the oxandrolone group. It should be noted that levels were reported only at the discretion of the principal investigators. No incidences of hepatic insufficiency were reported as adverse events by the investigators.

Table 4. Complications reported by investigators in subjects receiving placebo or oxandrolone

Complication	Placebo	Oxandrolone
Pneumonia	10	10
Line Infection	9	6
Urinary tract infection	6	7
Cellulitis	0	4
Increased liver enzymes	2	5
Deep venous thrombosis	3	2
Pulmonary embolism	1	1
Hyperglycemia	1	0
Small bowel obstruction	1	0
Wound infection	2	1
Lung abscess	1	0
Bronchopleural fistula	1	0
Renal failure	1	4
Graft loss	1	2
Urethral fistula	1	0
Herpes infection	1	1
Pneumothorax	1	0
Acute respiratory distress syndrome	2	0
Adrenal insufficiency	2	0
Nausea	1	0
Postoperative hemorrhage	2	0
Transfusion reaction	1	0
Elevated creatinine (not requiring dialysis)	1	1
Radial artery laceration	0	1
Rash	0	2
Gastrointestinal bleed	0	1
Decubitus ulcer	0	1
Atrial fibrillation	0	1
Confusion	0	2
Pleural effusion	0	1
Thrombocytosis	0	2
Sinusitis	0	1
Vocal cord granulomas	0	1
Corneal ulcer	0	1
Heterotopic ossification	0	1
Bronchial plugging	1	0
Infected thrombosed vein	1	0

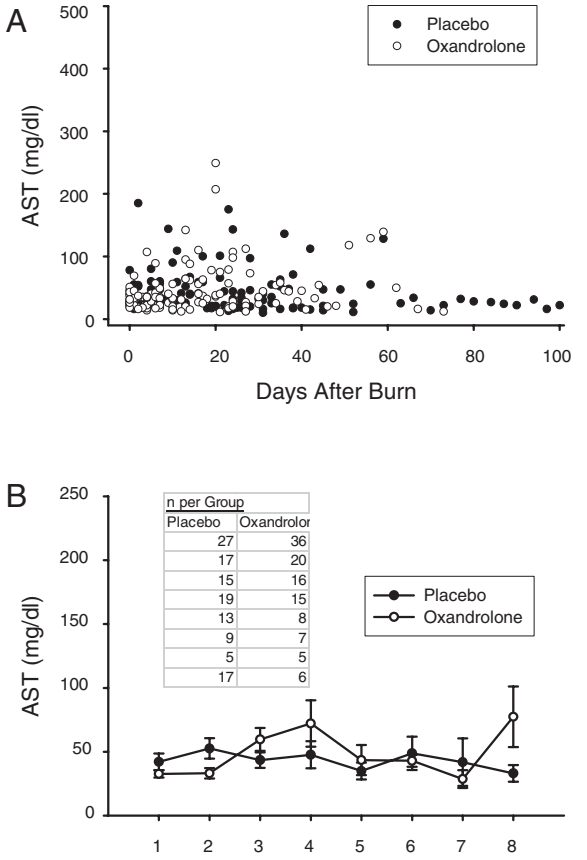

Figure 4. A. Dot plot of all measured aspartate aminotransferase levels in subjects receiving placebo or oxandrolone. One subject had values outside of 100 days, all of which were in the normal range and were not included. B. Data for aspartate aminotransferase levels grouped by weeks in placebo and oxandrolone subjects. Week 1 was considered to be from time of injury to 5 days (beginning of treatment). Week 8 contained values from week 8 of hospitalization and greater. No significant differences were found between groups (*t*-test with Bonferroni's correction). For the embedded table, the number of measurements (n) are listed in descending order for weeks 1 to 8.

DISCUSSION

This randomized placebo-controlled multicenter trial is the first conducted among burn centers testing the effects of the anabolic agent oxandrolone on outcome measures in burned adults. This study included 14 geographically distributed centers over a wide distribution of ages but was limited to burns of between 20% and 60% TBSA. We found that oxandrolone treatment given at 10 mg/kg every 12 hours by mouth or enteral feeding tube significantly decreased hospital length of stay. This association strengthened when deaths were excluded (four deaths in each group) and again strengthened when hospital length of stay was indexed to burn size. In fact, indexed hospital length of stay was diminished by 28% with oxandrolone treatment. Numbers of adverse events and complications were not different between groups. Hepatic transaminases in particular were examined, where a significantly greater number of inci-

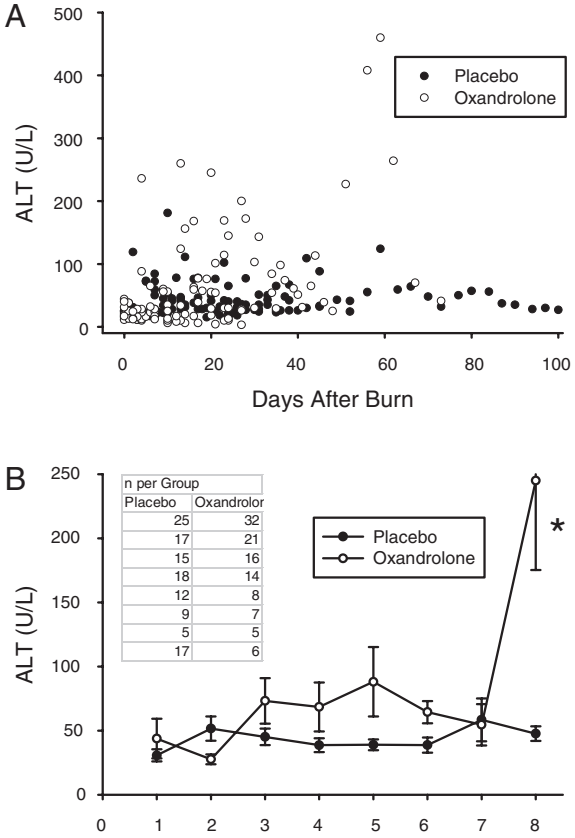

Figure 5. A. Dot plot of all measured alanine aminotransferase levels in subjects receiving placebo or oxandrolone. One subject had values outside of 100 days, all of which were in the normal range and were not included. B Data for alanine aminotransferase levels grouped by weeks in placebo and oxandrolone subjects. Week 1 was considered to be from time of injury to 5 days (beginning of treatment). Week 8 contained values from week 8 of hospitalization and greater. A significant difference between groups was found in week 8 ($P < .001$ by *t*-test with Bonferroni's correction). No other differences were found between groups. For the embedded table, the number of measurements (n) are listed in descending order for weeks 1 to 8.

dences of hepatic damage (ALT > 100 mg/dl) were detected with oxandrolone treatment (21 of 110 measurements). These data show that oxandrolone treatment is effective at decreasing hospital length of stay in the severely burned. Enthusiasm, however, should be tempered somewhat by the finding of potential hepatic damage. We suggest that oxandrolone treatment should be considered in all the severely burned while hepatic transaminases are monitored.

Multicenter trials among burn groups have been rare. One such randomized double-blinded trial determined treatment with a monoclonal antibody directed against intercellular adhesion molecule-1 improved spontaneous wound healing.[14] Another trial assessing infection and take rates of Integra™(Integra Life Sciences Corp., Plainsboro, NJ) among several centers also was undertaken. This study showed that Integra™ can be used safely, but it did not show efficacy.[15] It also was not blinded. Another multicenter study using Integra™ for reconstruction again noted it can be used safely; however, control patients were not used.[16] Fibrin sealant was assessed in another study, where it was shown to improve hemostasis in donor sites.[17] Autograft sites had improved appearance after coverage with Apligraf™ (Novartis, Basel, Switzerland) at operative placement compared with control sites[18]; again, this study was not blinded. Dermagraft-TC (Advanced Tissue Sciences, Inc., La Jolla, CA) was shown to improve autograft take when used to cover excised wound beds for at least 5 days.[19] Another trial assessing a human decellularized dermal matrix showed efficacy in graft take.[20] Yet another showed improved wound cleaning and healing with application of collagenase to burn wounds.[21] Multicenter studies published that showed no effect included one that showed no demonstrable effect of fibrin sealant on donor site bleeding,[22] whereas others showed no effect of immunotherapy with thymostimulin[23] or immunoglobulin.[24] This is the extent of controlled multicenter clinical trials in burned patients, and all but one of the aforementioned studies were funded by industry to assess the efficacy of their product. In this study, we assessed the effects of a drug given by mouth that has been approved for clinical use for weight loss since 1974, but its efficacy has not been tested in multiple centers or in severely burned adults for weight loss or other clinical outcomes. This study was performed without industry support, costs for laboratory examinations, and investigator time being borne completely by the individual centers. Some sites received medication from BTG Pharmaceuticals (Iselin, NJ). This study group previously published multicenter reports on purpura fulminans[25] and toxic epidermal necrolysis,[26] but this prospective trial is the first they have performed. This study demonstrates that large prospective placebo-controlled double-blind clinical trials can be initiated and completed among burn clinical investigators without significant industry support.

We found that treatment with oxandrolone decreased hospital length of stay in burned subjects. Reasons for this are not defined in the study but could be related to improved well-being with maintenance of more normal metabolism, decreased inflammation, improved organ function, and/or improved wound healing. We did find a significant decrease in operative procedures in the oxandrolone group,

which may account in part for the difference. Further analysis of this variable showed that the population receiving oxandrolone followed a normal distribution with a peak at one to two surgeries in terms of number of operations required, whereas those receiving placebo skewed toward more operations that may have been the result of following a bimodal distribution with peaks at one surgery and another at seven surgeries. Another explanation may be that more subjects with "harder" wounds and diminished wound healing were randomized to the placebo group and, thus, they required more operations for wound closure, which was not an effect of oxandrolone. Of course, this is a possibility with a probability of 4.2% ($P = .042$ for our primary outcome variable).

Hospital discharge often is linked to patient strength and ability to care for themselves, which was likely improved with treatment using anabolic steroids. This result should not be surprising, given the observation that men have greater levels of testosterone and have more strength on average. Observations of athletes allegedly taking anabolic steroids also supports this contention. Because of self-imposed limitations on the study in terms of number and complexity of investigations because of cost, we did not have the ability to demonstrate exactly why length of stay decreased. With more statistical power, we may have been able to show a decrease in ventilator days, implying improved strength, organ function, and well-being. Further data are being assessed on measures of inflammation, wound healing, and nutrition, which will be the subject of a future report.

Although we found a significant difference in hospital length of stay, we did not find a difference in hospital charges when reported by investigators. Reasons for this lack of difference may be related to increased variability with insufficient power to show differences or a relatively high charge for care early in the hospitalization that would be equally distributed between groups. Therefore, charges might have been linked to diagnostic-related groups (ie, DRGs) and other codes that would not reflect length of stay in the charge variable. Additional charges for days at the end of hospitalization were therefore insufficient to engender a statistical difference.

One of the goals of this study was to assess complications with oxandrolone treatment in the severely burned. We found roughly equivalent numbers of events in placebo and oxandrolone treated subjects. Qualitative analysis of the complications seem to intimate an increase in skin complications (cellulitis and rashes) and renal failure. This study, however, was insufficiently powered to show whether these events were truly more prevalent with oxandrolone treatment. Further observational studies might be performed to assess this possibility. It should be noted, however, that these events are common in burned patients, and it will be difficult to show causality of oxandrolone treatment. Prudence would suggest that burn clinicians using oxandrolone (which now has demonstrated efficacy on clinical outcomes with type 1 evidence) should be wary of these complications and take appropriate measures should they arise. Overall, complications do not appear to be increased with oxandrolone treatment. It is also possible that complications of oxandrolone treatment could arise well after hospitalization. Because of the limitations of the study design, this possibility was not assessed in these subjects, although no reports of delayed complications of oxandrolone used for therapy in ill patients are in the literature.

Increases in hepatic transaminases with oxandrolone treatment were observed in some patients with burns[10] and HIV infection.[7] To further assess whether this occurs in burned adults with 20% to 60% TBSA burns, we examined transaminase levels in our enrolled subjects. Transaminase levels were collected at the discretion of the principal investigators in response to perceived complications. We found that overall levels were not different between placebo and oxandrolone treated subjects except for ALT after 8 or more weeks of hospitalization and treatment with oxandrolone. However, the number of levels reported that were greater than 100 mg/dl were greater in the oxandrolone group, suggesting that treatment oxandrolone with can be associated with increased serum transaminases. The clinical relevance of this finding is unknown. We can clearly conclude from our data that increased transaminases are not associated with increases in length of stay or other complications. In fact, oxandrolone treatment was shown to improve 6-month mortality in those with alcoholic hepatitis with moderate malnutrition.[8] From our results, we suggest that oxandrolone prescription in burned patients should be performed with the knowledge that it can induce increased hepatic transaminases in the serum, and intermittent monitoring is suggested.

CONCLUSION

We showed that treatment with oxandrolone in patients with burns decreases length of hospital stay by 28% without significant increases in complications. For this reason, we suggest that oxandrolone treatment should be considered in all patients with burns greater than 20% of the body surface who are expected to be hospitalized for a length of time. Cau-

tion should be attended for potential increases in skin complications and hepatic elevation transaminase.

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